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Heinrich, Henriette ; Gubler, Christoph ; Valli, Piero V

Abstract: Over-the-scope-clips (OTSC®) have been shown to be an effective and safe endoscopic treatment option for the closure of gastrointestinal perforations, leakages and fistulae. Indications for endoscopic OTSC® treatment have grown in number and also include gastro cutaneous fistula (GCF) after percutaneous endoscopic gastrostomy (PEG) tube removal. Non-healing GCF is a rare complication after removal of PEG tubes and may especially develop in immunosuppressed patients with multiple comorbidities. There is growing evidence in the literature that OTSC® closure of GCF after PEG tube removal is emerging as an effective, simple and safe endoscopic treatment option. However current evidence is limited to the geriatric population and short standing GCF, while information on closure of long standing GCF after PEG tube removal in a younger population with significant comorbidities is lacking. In this retrospective single-center case-series we report on five patients undergoing OTSC® closure of chronic GCF after PEG tube removal. Four out of five patients were afflicted with long lasting, symptomatic fistulae. All five patients suffered from chronic disease associated with a catabolic metabolism (cystic fibrosis, chemotherapy for neoplasia, liver cirrhosis). The mean patient age was 43 years. The mean dwell time of PEG tubes in all five patients was 808 d. PEG tube dwell time was shortest in patient 5 (21 d). The mean duration from PEG tube removal to fistula closure in patients 1-4 was 360 d (range 144-850 d). The intervention was well tolerated by all patients and no adverse events occurred. Successful immediate and long-term fistula closure was accomplished in all five patients. This single center case series is the first to show successful endoscopic OTSC® closure of long lasting GCF in five consecutive middle-aged patients with significant comorbidities. Endoscopic closure of chronic persistent GCF after PEG tube removal using an OTSC® was achieved in all patients with no immediate or long-term complications. OTSC® is a promising endoscopic treatment option for this condition with a potentially high immediate and long term success rate in patients with multiple comorbidities.

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Over-the-scope-clip closure of long lasting gastrocutaneous fistula after percutaneous endoscopic gastrostomy tube removal in immunocompromised patients: A single center case series

Henriette Heinrich, Christoph Gubler, Piero V Valli

Henriette Heinrich, Christoph Gubler, Piero V Valli, Division of Gastroenterology and Hepatology, University Hospital Zurich, CH-8091 Zurich, Switzerland

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Correspondence to: Christoph Gubler, MD, Division of Gastroenterology and Hepatology, University Hospital Zurich, Raemistrasse 100, CH-8091 Zurich, Switzerland. christoph.gubler@icloud.com
Telephone: +41-44-2553642
Fax: +41-44-2554474

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Abstract

Over-the-scope-clips (OTSC®) have been shown to be an effective and safe endoscopic treatment option for the closure of gastrointestinal perforations, leakages and fistulae. Indications for endoscopic OTSC® treatment have grown in number and also include gastro cutaneous fistula (GCF) after percutaneous endoscopic gastrostomy (PEG) tube removal. Non-healing GCF is a rare complication after removal of PEG tubes and may especially develop in immunosuppressed patients with multiple comorbidities. There is growing evidence in the literature that OTSC® closure of GCF after PEG tube removal is emerging as an effective, simple and safe endoscopic treatment option. However current evidence is limited to the geriatric population and short standing GCF, while information on closure of long standing GCF after PEG tube removal in a younger population with significant comorbidities is lacking. In this retrospective single-center case-series we report on five patients undergoing OTSC® closure of chronic GCF after PEG tube removal. Four out of five patients were afflicted with long lasting, symptomatic fistulae. All five patients suffered from chronic disease associated with a catabolic metabolism (cystic fibrosis, chemotherapy for neoplasia, liver cirrhosis). The mean patient age was 43 years. The mean dwell time of PEG tubes in all five patients was 808 d. PEG tube dwell time was shortest in patient 5 (21 d). The mean duration from PEG tube removal to fistula closure in patients 1-4 was 360 d (range 144-850 d). The intervention was well

tolerated by all patients and no adverse events occurred. Successful immediate and long-term fistula closure was accomplished in all five patients. This single center case series is the first to show successful endoscopic OTSC® closure of long lasting GCF in five consecutive middle-aged patients with significant comorbidities. Endoscopic closure of chronic persistent GCF after PEG tube removal using an OTSC® was achieved in all patients with no immediate or long-term complications. OTSC® is a promising endoscopic treatment option for this condition with a potentially high immediate and long term success rate in patients with multiple comorbidities.

Key words: Gastro cutaneous fistula; Endoscopic fistula closure; Over-the-scope-clips; Percutaneous endoscopic gastrostomy; Fistula in immunosuppressed patients

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Core tip: Over-the-scope-clips (OTSC®) are effective and safe for closure of gastrointestinal perforations, leakages and fistulae. There is growing evidence that OTSC® can be applied for the closure of gastrocutaneous fistula after percutaneous endoscopic gastrostomy (PEG) tube removal. In this retrospective single-center case-series we report on five middle-aged patients with multiple comorbidities undergoing OTSC® closure of chronic gastro cutaneous fistula after PEG tube removal. The mean dwell time of PEG tubes was 808 d. Successful immediate and long-term fistula closure was accomplished in all five patients. OTSC® is a promising treatment for this condition with a high immediate and long-term success rate.

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INTRODUCTION

The application spectrum of the over-the-scope-clip (OTSC®) has continually evolved from hemostasis to closure of gastrointestinal perforations, leakages and fistulae including anorectal lesions^[1-7]. OTSC®s have been proven to be an effective and safe endoscopic treatment option in these conditions^[2,8-10]. Emerging indications include fixation of self-expandable metallic stent (SEMS) and diameter reduction of gastrojejunal anastomosis after gastric bypass.

Non-healing gastrocutaneous fistula (GCF) is a rare complication after removal of percutaneous endoscopic gastrostomy (PEG) tubes and can be treated surgically or endoscopically^[11]. Clip application, suture, gluing, banding^[12] and coagulation techniques have been de-

scribed as endoscopic therapeutic options^[13-17]. Nevertheless, OTSC® application is emerging as a simple and safe endoscopic treatment for persistent GCF.

Even though various risk factors for the development of GCF such as stomal infection, delayed gastric emptying, acid hypersecretion, malnutrition, catabolic metabolism, tumors, immunosuppression and consecutive impaired wound healing have been discussed, the only evidence-based risk factor is a duration of gastrostomy > 6 mo leading to epithelialization and persistence of the gastrostomy channel^[18,19]. Existing case series on OTSC® application for GCF closure generally focus on closure of short standing GCFs in the setting of infection in geriatric populations^[2,8]. We here report on our experience with OTSC® closure of long standing GCF in middle-aged patients with significant comorbidities.

CASE REPORT

We report five cases of patients who were treated in one tertiary care center and underwent closure of persisting GCF after PEG tube removal. Since the OTSC® has been implemented into daily routine, five patients were referred to our clinic for endoscopic closure of persistent GCF after PEG tube removal. After thorough evaluation of each case and written informed consent by each patient, procedures were performed with flexible Olympus® endoscopes using carbon dioxide insufflation instead of ambient air.

The deployment of OTSC® has been published before^[20]. A "beardaw" like OTSC® clamped on a plastic cap is mounted onto the tip of the endoscope. The targeted lesion is then pulled into the plastic cap by suction. If the surrounding tissue is fibrotic and scarred a three-hook anchoring device (anchor® OVESCO Endoscopy AG, Tübingen) is used. The OTSC® is then deployed over the targeted lesion.

Primarily, the smallest, atraumatic (a) OTSC® (size 11 mm) was chosen in order to easily pass the upper esophageal sphincter and to minimize lacerations within the esophagus. In one patient, the largest OTSC® (size 14 mm) was necessary to achieve tight GCF closure after a size 12 OTSC® failed to do so. The small-sized OTSC® was removed with a standard rat-tooth forceps. No overtube was necessary to introduce the OTSC® mounted endoscope. Immediate evaluation of closure success was either proven endoscopically or utilizing contrast medium and inspection of the fistula orifice at skin level. Lasting closure success and subsequent complications were assessed clinically in the follow-up.

Between June 23rd 2009 and June 18th 2015, a total of 1373 PEG tubes were inserted at our clinic. We removed 231 of these PEG tubes in the follow-up. A total of 4 patients (0.29%) developed chronic GCF and were then referred to our unit for endoscopic closure (Table 1). Immediate OTSC® closure of the gastrostomy was performed upon PEG tube removal in a fifth patient due to ascitic fluid leakage. All 5 patients suffered

Table 1 Patients developed chronic gastro cutaneous fistula and were then referred to our unit for endoscopic closure

	Age	Gender	Underlying condition	No. of previous PEG's	Date of first PEG	Date of PEG removal	Duration of PEG treatment	PEG complication	Age of GC fistula (d)	Previous antibiotics	OTSC type	Date of OTSC placement	Method	Successful immediate closure	Long term resolution of leak	Follow-up (d)	Complications
Case 1	67	F	Cerebral ischemia, tongue carcinoma	3	23/07/09	20/01/11	546	Chronic, recurrent infections with gastrocutaneous fistula	203	Yes	11/3a	11/08/11	Suction and anchor	Yes	Yes	1875	No
Case 2	23	F	Cystic fibrosis	1	31/12/11	01/06/15	1248	Persisting gastrocutaneous fistula	241	No	11/6a	28/01/16	Suction	Yes	Yes	244	No
Case 3	23	M	Cystic fibrosis	1	30/07/12	18/06/15	1053	Persisting gastrocutaneous fistula	144	No	11/6a	09/11/15	Suction	Yes	Yes	324	No
Case 4	52	F	Oropharyngeal carcinoma	1	30/12/11	18/01/13	385	Persisting gastrocutaneous fistula	850	No	11/6a	18/05/15	Suction	Yes	Yes	499	No
Case 5	52	M	Tongue carcinoma liver cirrhosis	1	23/08/12	13/09/12	21	Leaking gastrostomy due to ascites	NA	No	14/6a	13/09/12	Suction	Yes	Yes	1476	No
Mean	43						808		360							884	

PEG: Percutaneous endoscopic gastrostomy; OTSC: Over-the-scope-clips; F: Female; M: Male; NA: Not applicable.

from chronic disease associated with a catabolic metabolism (cystic fibrosis, chemotherapy for neoplasia, liver cirrhosis). Patients 2 and 3 had cystic fibrosis and required additional feeding through a PEG tube due to malnutrition. Patient 1, patient 4 and patient 5 suffered from tongue or oropharyngeal carcinoma, respectively and needed PEG-feeding during radio-chemotherapy. Patient 5 additionally suffered from refractory ascites due to decompensated liver cirrhosis. The mean age of the patients was 43 years. The mean duration of prior PEG treatment was 808 d (d) in all 5 patients while the time period was shortest in patient 5 (21 d).

Patient 1 suffered from chronically infected PEG sites necessitating antibiotic treatment applying various different regimes and following two changings of the PEG site. Upon suction during OTSC® placement, pus drained through the fistula towards the endoscope (Figure 1). Three patients (patients 2-4) suffered from a chronically draining and persisting GCF after PEG tube removal. Patient 5 suffered from refractory ascites due to decompensated liver cirrhosis complicated by bacterial peritonitis following PEG insertion. Therefore, immediate and tight OTSC® closure of the gastrostomy was performed immediately after PEG tube removal.

The mean duration from PEG tube removal to fistula closure in patients 1-4 was 360 d (range 144-850 d).

A small sized OTSC® (size 11 mm) was sufficient in patients 1-4 to achieve successful and tight fistula closure. In patient 5, a size 12 mm OTSC® was chosen for the first closure attempt. After deployment, leakage of ascites into the stomach was noticed suggesting incomplete closure. Therefore, the 12 mm OTSC® was removed using a standard rat-tooth forceps. In a second attempt during the same procedure ascites-tight closure of the GCF was accomplished. In patient 1, we used suction and the anchoring device for appropriate clip deployment. Suction through the working channel of the endoscope alone was then sufficient for adequate clip placement in all the four cases that followed.

Successful immediate GCF closure was accomplished in all 5 patients. After a mean follow-up time of 746 d (range 186-1737 d), all five leaks showed persistent long-term fistula closure. All clips remained in place with some overgrowing granulation tissue, but patients were asymptomatic; no abdominal discomfort or pain was reported. No OTSC® associated complications occurred and none of the clips had to be removed. On a skin level, scarring and retraction at the PEG site were minimal.

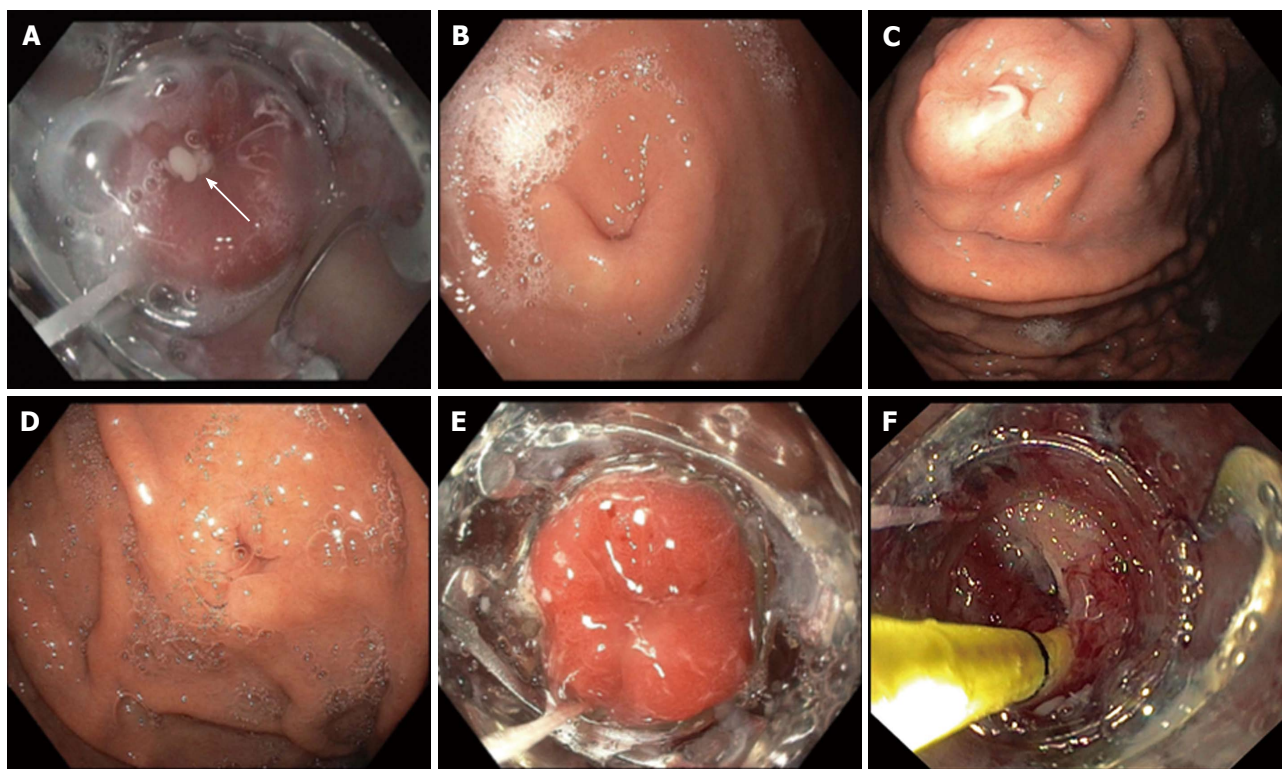


Figure 1 Upon suction during over-the-scope-clips placement, pus drained through the fistula towards the endoscope. A: Patient 1, arrow indicates pus; B: Patient 2; C: Patient 3; D: Patient 4; E: Patient 4, fistula after OTSC deployment; F: Patient 5, alignment of OTSC using a guide wire. OTSC: Over-the-scope-clip.

DISCUSSION

We present the first single-center case series showing successful endoscopic GCF closure using the OTSC® device in middle-aged patients suffering from severe comorbidities. Since the introduction of the PEG in 1980 by Gauderer *et al*^[21] surgery has been the treatment of choice for persisting GCF. Before the introduction of the OTSC®, the endoscopic armamentarium for GCF closure comprised mainly clip application, suture, gluing and coagulation techniques^[13-17]. Alongside with the evolution of interventional endoscopy, the OTSC® device has gained significant importance as a sophisticated closure tool for various gastrointestinal conditions. The classical indications for OTSC® treatment are gastrointestinal perforations^[3], leakages^[4], fistulae^[5] and uncontrolled bleedings^[22]. These classical indications have lately been broadened to include SEMS fixation^[23], closure of Peroral Endoscopic Myotomy access^[24] within the esophagus as well as diameter reduction of gastrojejunal anastomosis after gastric bypass^[25]. As recently shown by our group in a large cohort^[26], traumatic or inflammatory fistulae are the most challenging conditions in regards to closure success rate. OTSC® closure of persisting GCF after PEG tube removal is a specific subgroup within this fistula group and is thus not comparable to classic chronic GCF in other conditions in regards to closure efficacy. We argue, based on our results, that due to the removal of the inserted foreign body (PEG tube) and the absence of chronic inflammation, OTSC® closure in GCF

is far more promising in regards to successful closure compared to self-developing inflammatory fistulae. Long-term immunosuppressive therapy is a known risk factor for impaired wound healing and might therefore promote persistence of GCF after PEG removal. Catabolic metabolism in chronically ill patients seems to have the same effect. Geriatric patients are prone to suffer from persisting GCF suggesting that age itself is a risk factor for impaired natural closure of the PEG tunnel. Our mean patient age (43 ± 24 years) was significantly lower compared to the only existing comparable case series by Singhal *et al*^[2] (mean age 84.4 ± 8.75 years). Yet, all of our patients suffered from chronic disease associated with a catabolic metabolism. We therefore suggest, that the patients' tissue regeneration was compromised allowing the PEG tunnel to persist after tube removal. Once a chronic GCF is triggered by an immunocompromised state of any origin, the GCF still differs much from conventional inflammatory fistulae in the gastrointestinal tract. This fact might be due to the integrity of the tissue surrounding the fistula orifice in GCF compared to the damaged surrounding tissue in inflammatory fistulae. Therefore, effective clip placement and persistent attachment is far more challenging in inflammatory fistulae. In addition to the immunocompromised state, four out five patients underwent a long-term PEG treatment (> 6 mo) as the main risk factor for developing persistent GCF after PEG tube removal^[18,19].

Portal hypertension with tense ascites is known

to hinder closure of abdominal wall fistulae^[27,28]. We therefore decided to immediately close the GCF in patient 5 after PEG tube removal. Whether or not previous gastropexies play a role in this particular setting is unknown. Since we so far only treated one patient with ascites for closure after PEG tube removal, a general recommendation cannot be given yet. Until there will be more data available in the future, individual solutions will need to be sought for.

Even though the number of patients in our case series is relatively small, our high closure success rate (100%) is in accordance with the success rate presented by Singhal *et al*^[2] (90%). These results stand in clear contrast to the low long-term success rate of 30% published by our group for inflammatory fistulae^[26]. Compared to Singhal *et al*^[2], our follow-up period was clearly longer and shows that there is a low rate of long term failures after endoscopic fistula closure. Although the OTSC® is a foreign body with a drop-off rate of 0% in our case series, the clips did not induce any symptoms and no need for removal arose.

No major complications connected to the OTSC® treatment were recorded in our study. In one case, a too small-sized OTSC® was chosen initially and failed to achieve tight GCF closure. The clip was easily removed with a standard forceps and did not interfere with a second deployment of a larger sized OTSC®. In case of strong clip adherence or any other indication for clip removal, OVESCO Endoscopy AG (Tübingen) has introduced an OTSC® clip cutter system. In our large OTSC® cohort published previously, only a few minor complications occurred (in 6 out of 233 cases)^[26]. These included accidental deployment of the OTSC® on the patients' tongue in the very first cases and superficial mucosal laceration of the esophagus due to a too large-sized OTSC®.

In this case series, we adapted the clip size to the particular features of the GCF, the patient and the clinical setting. We used one size 14 clip, which can cause difficulties in passing the upper esophageal sphincter due to its large diameter. Compared to the study of Singhal *et al*^[2] and Sulz *et al*^[8], we included patients suffering from substantially more long standing GCF (mean fistula age = 360 d). Wright *et al*^[29] performed electrocautery of the GCF before clip closure. Unfortunately, the authors did not discuss the reason for this step before OTSC® closure in their publication. One could hypothesize that the granulation tissue caused by electrocautery would promote GCF healing. Even though we did not perform this step, we were able to show that even epithelialized, long-lasting PEG fistulas should not be excluded from an endoscopic closure attempt using the OTSC® device.

In conclusion, endoscopic closure of persistent GCF after PEG tube removal using an OTSC® is a promising indication with a potentially high immediate and long term closure rate and with limited complications to be feared.

COMMENTS

Case characteristics

Five middle-aged patients with severe comorbidities developed gastrocutaneous fistula (GCF) after percutaneous endoscopic gastrostomy (PEG) tube removal. Four patients had long-standing symptomatic fistulas (mean PEG dwell time 808 d), while one patient developed a leaking gastrostomy due to ascites.

Research frontiers

Over-the-scope-clips (OTSC®) application in the gastrointestinal tract is safe and effective in large variety of indications. There is evidence in the literature that OTSC application is safe and effective for endoscopic closure for GCF after PEG tube removal. However this evidence is mostly limited to a geriatric population with short standing GCFs.

Innovations and applications

This case series is the first to our knowledge to show safe and effective closure of GCF after PEG tube removal in a middle-aged patient population with severe comorbidities and long standing GCF.

Terminology

OTSC application for GCF closure after PEG Tube removal.

Peer-review

The manuscript provides anecdotal support for the application of OTSC for long standing GCFs after PEG removal.

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